ESTABLISHING THE MINIMAL SUFFICIENT NUMBER OF MEASUREMENTS TO VALIDATE A 24H BLOOD PRESSURE RECORDING

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Background: Ambulatory blood pressure (BP) monitoring (ABPM) remains a reference standard but the number of readings required to make the measurement valid has not been empirically validated.

Methods: Among 360 patients with chronic kidney disease and 38 healthy controls, BP was recorded 2 per hour during the night and 3 per hour during the day over 24h using a validated ABPM device; all had at least 90% of the expected readings. From this full set of ABPM recording, a variable number of BP measurements were selected and we compared the performance of the selected readings against that of the full sample using random or sequential selection schemes. To address the question whether random or sequential selection schemes affect the diagnostic performance in diagnosing hypertension control we compared the diagnostic decisions reached with the subsample and the full sample using area under the receiver operating-characteristic curves (AUC ROC). To answer the question regarding the number of readings needed to achieve over 90% coverage of the mean BP of the full ABPM sample we ascertained the point and confidence interval (CI) estimates based on the selected data.

Results: To diagnose hypertension control, the number of readings randomly drawn to establish lower bound with 2.5% error of area under the receiver operating-characteristic curve (AUC ROC) of 0.9 was 3, 0.95 was 7, and 0.975 was 13 . In contrast, the corresponding number of readings with serial selections was 18, 30 and 39

respectively. With a random selection scheme, 18 readings provided 80% coverage of the 90th percentile of CI of the true systolic BP mean, for 90% coverage, 26 readings were needed, for 95% coverage 33. With serial selections, the number of readings increased to 42, 47, and 50 respectively. Similar results emerged for diastolic BP. Conclusions: For diagnosing hypertension control 3 random measurements or 18 serial measurements is sufficient. For quantitative analysis, the minimal sufficient number of 24h ambulatory BP is 26 random recordings or 42 serial recordings.

Wanzhu Tu, PhD, Committee Chair

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List of Abbreviations

ABPM	Ambulatory blood pressure monitoring
ACE	angiotensin converting enzyme
AUC	area under curve
BP	Blood pressure
CARDIA	Coronary Artery Risk Development in Young Adults
CI	confidence interval
CKD	Chronic kidney disease
ESH	European Society of Hypertension
GFR	glomerular filtration rate
IDACO	International Databases of Ambulatory Blood Pressure in relation to Cardiovascular Outcome
NICE	National Institute of Clinical Excellence
ROC	receiver operating-characteristic curve
UK	United Kingdom
USPTF	United States Preventive Task Force

Chapter One

Introduction

Ambulatory blood pressure (BP) monitoring (ABPM) over 24h is considered the reference standard for both making a diagnosis of hypertension and to assess its control (1). Not only it provides qualitative data regarding diagnosis or control of hypertension, but ABPM is also used commonly to assess changes with antihypertensive therapy. However, what constitutes an adequate BP recording has never been empirically tested and is a matter of opinion. These opinions are embodied in various guidelines and some large studies.

The European Society of Hypertension Guidelines 2013 (2) state,

> "There are no firm data on which to base recommendations for a satisfactory ABPM recording, but the recommendation for having at least 70% of expected measurements provides a basic working recommendation for clinical practice. …In the previous ESH guideline on measurement, it was recommended that there should be a minimum of 14 measurements during the day and seven measurements at night. Having considered what evidence is available and the practical issues of performing repeat ABPM in practice, it seems reasonable to increase the minimum of daytime measurements to 20 while retaining a minimum seven measurements at night based on measurements being performed every 30 min with fixed time periods being used to define day (0900 to 2100h) and night (0100 to 0600h)".

The ESH Guidelines 2013 (2)recommend repeating ABPM for the following 3 reasons: (i) there are not at least 70% of the expected measurements over 24h; (ii) there are fewer than 20 readings during the awake period (0900 to 2100 h); and (iii) there are fewer than 7 recordings during the sleep period (0100 to 0600 h). Furthermore, for research purposes, the ESH guidelines suggest that the recording be repeated if there are fewer than 2 recordings per hour during the day and 1 per hour during the night.

The UK NICE guidelines 2011 (3) state, “When using ABPM to confirm a diagnosis of hypertension, ensure that at least two measurements per hour are taken during the person’s usual waking hours (for example, between 08:00 and 22:00). Use the average value of at least 14 measurements taken during the person’s usual waking hours to confirm a diagnosis of hypertension.”

The American Heart Association guidelines have no stated position on how many measurements of ABPM are required for the recording to be considered adequate (4).

Other large studies published their own criteria. For example, The Coronary Artery Risk Development in Young Adults (CARDIA) Study (5) “defined nighttime as midnight to 0600 and daytime as 1000 to 2200. For a session to be deemed adequate, we required a minimum of 10 daytime measurements and 5 nighttime measurements during these specific intervals.”

The International Databases of Ambulatory Blood Pressure in relation to Cardiovascular Outcome (IDACO) required at least 10 daytime and at least 5 nighttime recordings to be considered further for analysis (6).

None of the above recommendations is based on empirical data. The ESH requirement of at least 70% of expected recordings including at least 20 during the day and at least 7 during the night are strict. Adherence to these guidelines may mean repeating ABPM, which the patients may not agree to perform. This may lead to missing data, which bias the results of the study because those participants in a clinical trial who adhere to ABPM protocol may also have positive health behaviors. Those who do not adhere may also not take their medications or adhere to positive behaviors.

Thus, data may not be missing completely at random. Informative censoring of the observation may therefore influence results.

The purpose of this study was to answer the question of how many recordings are needed for ABPM to be considered adequate. Furthermore, we asked the question whether pre-specified thresholds are needed for daytime and nighttime recordings for the ABPM to be considered adequate.

Chapter Two

Methods

Patients and BP measurements

Patients with chronic kidney disease (CKD) and hypertension were recruited from the renal clinic at Roudebush Veteran's Administration hospital in Indianapolis. Normotensive controls with no evidence of CKD or cardiovascular disease were recruited from the medicine clinic of the same hospital.

Ambulatory BP monitoring was performed over 24h using the SpaceLabs 90207 monitor, (SpaceLabs, Issaquah, WA) that has been validated (7). The monitor was programmed to record BP every 20 minutes from 0800h to 2200h and every 30 minutes from 2200h to 0800h as reported previously (8).

The study was approved by the Indiana University Institutional Review Board and the VA Research and Development Committee and all participants signed a written informed consent.

Diagnosis of hypertension

In this report, in each patient at least 23 of the 24-hour recordings were available for analysis. The diagnosis made based on the full sample were considered the gold standard in this report. A diagnostic decision was made for each individual patient based on following criteria. Patients with mean 24h ambulatory systolic BP ≥ 130 mmHg or diastolic BP ≥ 80 mm Hg were classified as hypertensive (if not on BP medications) or poorly controlled hypertensives (if receiving antihypertensive medications). Besides the 24h recordings, we analyzed the data separately for daytime (0900 to 2100h) and

nighttime (0100 to 0600). These times for definitions of day and night were chosen on the recommendation of the ESH guidelines. Daytime hypertension was diagnosed with BP ≥135 systolic or ≥85 mmHg diastolic and nighttime hypertension with BP ≥125 systolic or ≥75 mmHg diastolic.

Sampling and analysis

In this research, we considered two different sampling schemes: (1) A random sampling plan that randomly selected a predetermined number (m) of readings from each patient; (2) A serial sampling plan that randomly selected a series of sequential BP readings of size m.

Qualitative analysis of diagnosis of hypertension

We performed the analysis of the selected readings and compared the diagnostic decision against that from the full data. Specifically, we calculate the mean systolic and diastolic BP. Diagnoses were made based on the calculated mean systolic and diastolic BP from the selected readings. We then compared the diagnosis based on the selected subsample to the gold standard. For making a diagnostic decision, we calculated the area under curve (AUC) of the receiver operating-characteristic curve (ROC) and its 95% confidence interval (CI). The gold standard for the outcome was the full set of 24h ABPM recordings. We then repeated the process iteratively and calculated the AUC under ROC and its 95% CI. A high AUC under ROC especially when the lower limit of the 95% CI exceeded the 0.9 ROC threshold suggested that the size of the subsample was sufficient to reach the same diagnostic decision as the full ABPM. For each given m, we repeated the random experiment 1000 times. We increased the number of selections

from x to y to determine the optimal number of readings needed to reach convergence to a decision reached by the full dataset. We performed these analyses for the 24h data set and for daytime and nighttime recordings separately.

Quantitative analysis of agreement with full data set

To answer the second question posed by the study, we calculated 90% CIs for the mean systolic and diastolic BP. We then determine the proportions of times that the calculated CI covered the gold standard means. From the calculated CIs, we determined the proportion of times that the interval covered the gold standard means and the average lengths of the intervals for each given m. Empirical coverage probability approach the nominal level (90%) and shorter interval lengths indicated the accuracy and precision of the subsamples, as the number of selected readings changed.

Chapter Three

Results

Of the 398 patients evaluated, 360 had hypertension and CKD whereas 38 were healthy controls. For the entire cohort the average age (SD) was 68.6 ± 9.3 years, 389 (97.7%) were men, 320 (80.4%) were white, 65 (16.3%) black, 232 (58%) had diabetes mellitus, 67 (16.8%) were current tobacco users, 68 (17.1%) had a history of heart failure, 109 (27.4%) history of myocardial infarction, 44 (11.1%) stroke, and 76 (19.1%) peripheral vascular disease. The mean body mass index was 30.3 ± 4.7 kg/m^2 and their estimated GFR was 48 ± 20.2 mL/min/1.73m^2. Of those who had hypertension, the mean number of medications was 3.1 ± 1.4. Loop diuretics were used by 37%, thiazides 25%, ACE inhibitors 54%, ARBs 20%, □-blockers 68%, and dihydropyridine calcium-channel blockers by 43%.

Actual ambulatory BP data from all 398 participants were analyzed. Patients had at least 23 h or recording with a range of 46 to 73 measurements per patient. The mean ambulatory and seated clinic oscillometric BP are shown in **Table 1**.

Table 1: Blood pressure measurements

Clinical characteristic	CKD	Healthy	p
n	360	38	
24h ABPM systolic (mmHg)	126.8 ± 13.5	121.7 ± 8.7	0.025
24h ABPM diastolic (mmHg)	69.2 ± 8.6	73.1 ± 6.0	0.006
Clinic BP systolic (mmHg)	119.8 ± 16.6	115.7 ± 11.0	0.13
Clinic BP diastolic (mmHg)	59.8 ± 10.7	64.7 ± 7.9	0.007

Clinic pulse rate (/min)	66.8 ± 11.8	69.7 ± 11.3	0.15

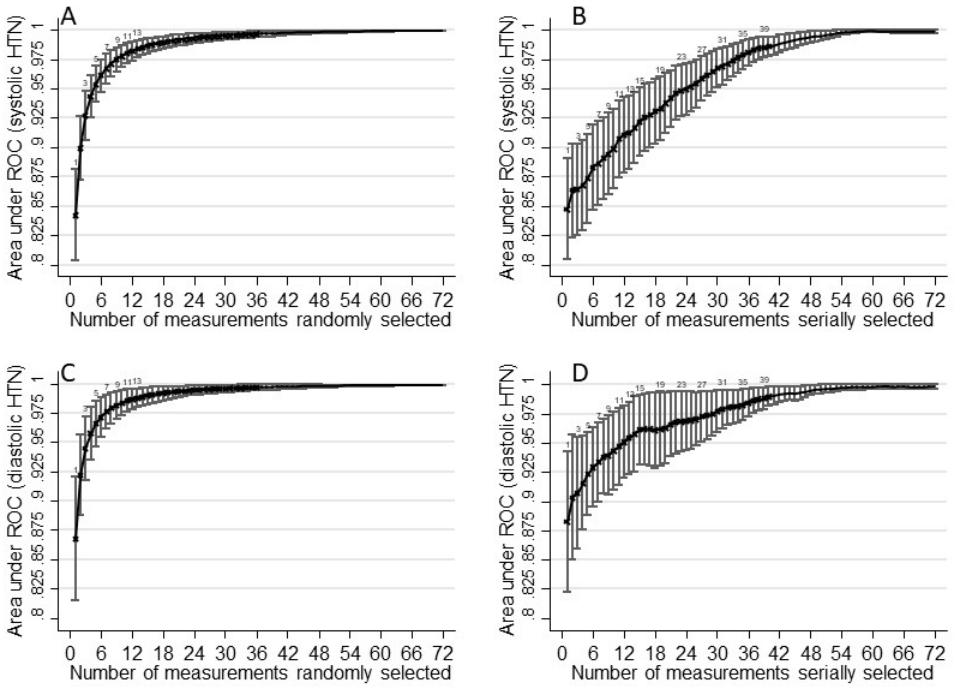


Figure 1

Figure 1: **Qualitative analysis of the diagnosis of hypertension control with increasing number of BP measurements**. Each graph plots area under the receiver operating-characteristic curve (AUC ROC) with increasing number of BP measurements selected from the full set. The reference set was the full set of recordings. Panel A and B show systolic and C and D diastolic recordings. The left panel shows readings selected at random from the full set. The right panel show serial selections of readings. As expected, increasing numbers of readings increased the confidence in making a diagnosis of hypertension control. Fewer recordings were needed when readings were selected at random, than when readings were selected serially. The I bars on the left panel are 1.96 x standard deviation and on the right panel 1.96 x standard error. The numbers on the top of I bars correspond to the number of measurements for clarity of interpretation of the data.

The results of diagnostic performance of the random and serial selections of ABPM are shown in **Figure 1**. Even with one available recording, whether it be random

(Figure 1A) or serial (Figure 1B), the AUC under ROC curve to make a diagnosis of hypertension or its absence was 0.80 or better. The error bars are based on 1000 simulations.

In the case of random selections, there was <2.5% chance that the AUC under ROC was <0.8 for just 1 randomly measured value. With 3 random measures, there was <2.5% that the AUC under ROC was <0.9, with 7 random measures there was <2.5% that the AUC under ROC was <0.95, and with 13 random measures there was <2.5% that the AUC under ROC was <0.975 (**Figure 1A**). Similar results were seen with diastolic BP recordings (**Figure 1C**).

In the case of serial selections, even the first measurement had AUC of 0.85 or better but with wide CIs (**Figure 1B**). For systolic recordings 18 and for diastolic recordings 6 were needed for the lower limit of CI to be >0.9. In contrast to random selection of BP, a greater number of serial recordings were needed to make a diagnosis of hypertension with ambulatory BP monitoring (**Figure 1B and 1D**).

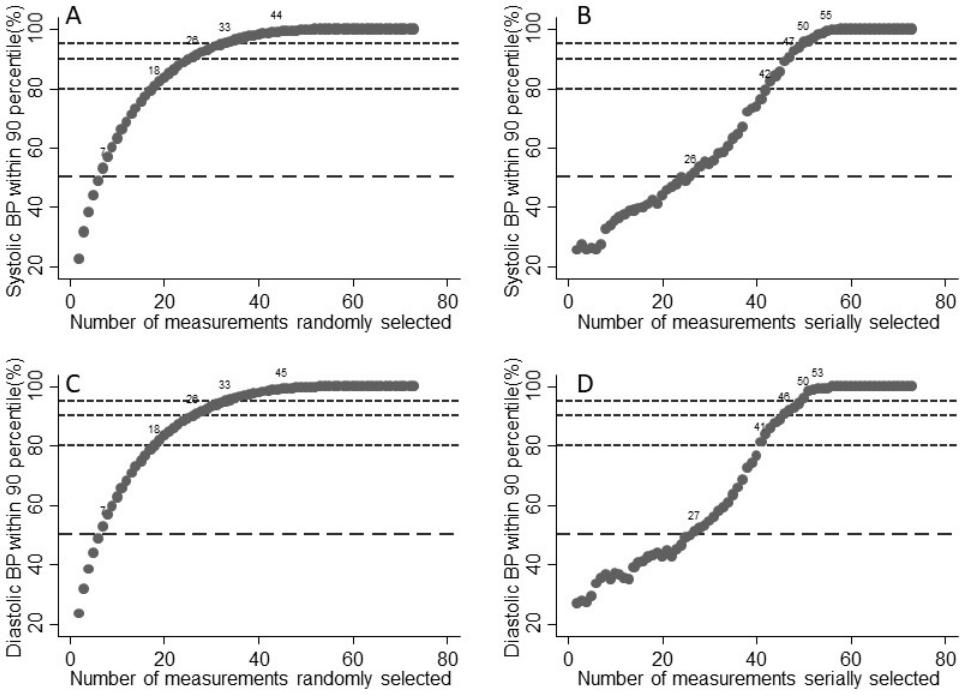


Figure 2

Figure 2: **Quantitative analysis of agreement of specific BP value with the true level of BP**. Each graph plots the number of recordings within 90th percentile of the true value. The mean 24h BP was taken to represent the true value of BP. As in Figure 1, Panel A and B show systolic and C and D diastolic recordings. The left panel shows readings selected at random from the full set. The right panel show serial selections of readings. As expected, increasing numbers of readings increased the coverage probability. Fewer recordings were needed when readings were selected at random to be within a coverage region, than when readings were selected serially. The numbers on the top of symbols correspond to the number of measurements for clarity of interpretation of the data.

Figure 2 plots the number of BP recordings versus the percent of readings that would lie within the 90% confidence limits of the true measurement. Random selection from these measurements increasing 1 at a time shows that just 18 readings were needed to be 80% certain that the mean value of systolic BP was within the 90 percentile CI of the true mean (**Figure 2A**). For 90% certainty, this number increased to

26, for 95% certainty, this increased to 33 readings. For 99% certainty, the number of readings needed was 44. With 7 recordings, there was only a 50% chance that the mean reading will be within the 90 percentile CI of the true mean.

Similar results were seen for diastolic BP recordings (**Figure 2C**). There was only one difference in that for 99% certainty, that the mean value of diastolic BP was within the 90 percentile CI of the true mean the number of readings needed was 45.

Next, we performed serial selections of the number of measurements—instead of random selections. With serial selections, in general, the number of readings that were needed to be confident that the mean systolic BP would lie within the 90 percentile CIs of the true mean was greater. In contrast to random selection where just 18 readings were needed to be 80% certain that the mean value of systolic BP was within the 90 percentile CI of the true mean, this number for serial selection was 42 (**Figure 2B**). For 90% certainty, this number increased to 47, for 95% certainty, this increased to 50 readings, and for 99% certainty, this number increased to 55. With 26 serial recordings, there was only a 50% chance that the mean reading will be within the 90 percentile CI of the true mean. Similar results were seen for diastolic BP (**Figure 2D**). Compared to 24h measurements, for daytime **(Figure 3)** and nighttime **(Figure 4)** measurements, the number of readings taken were lower. Not surprisingly, the probability to be 50, 80, 90, and 95% certain that the measurements were within the 90 percentile of the true mean were lower (**Table 2**). Similar results emerged for diastolic BP.

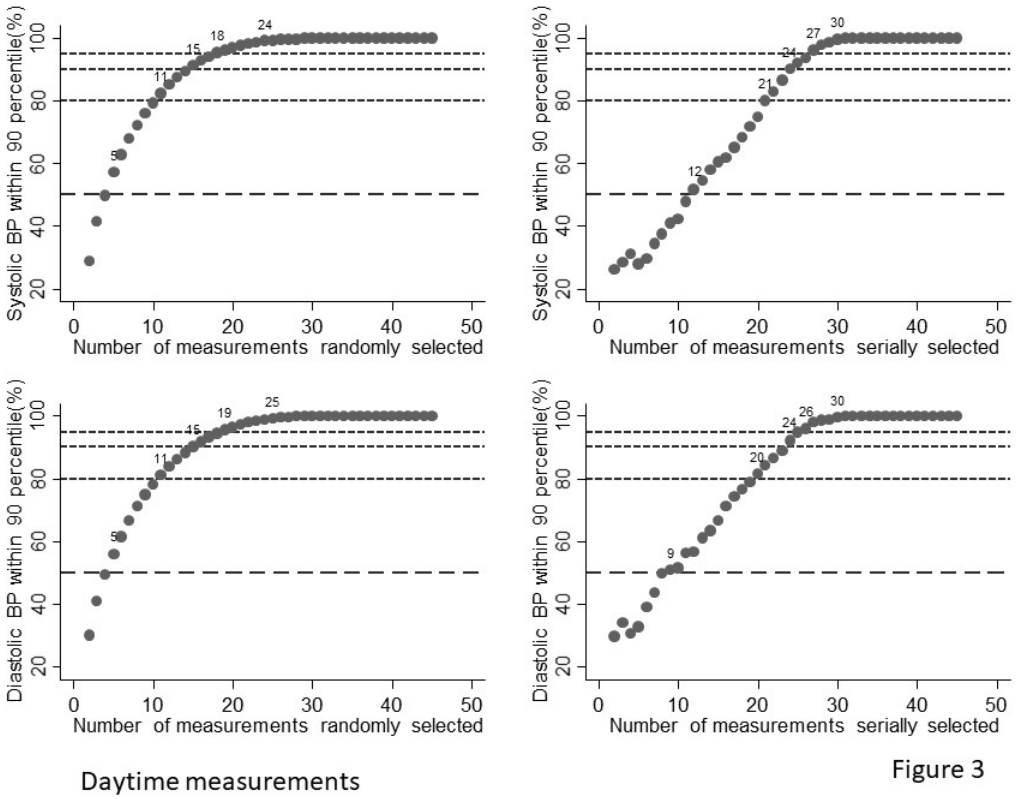
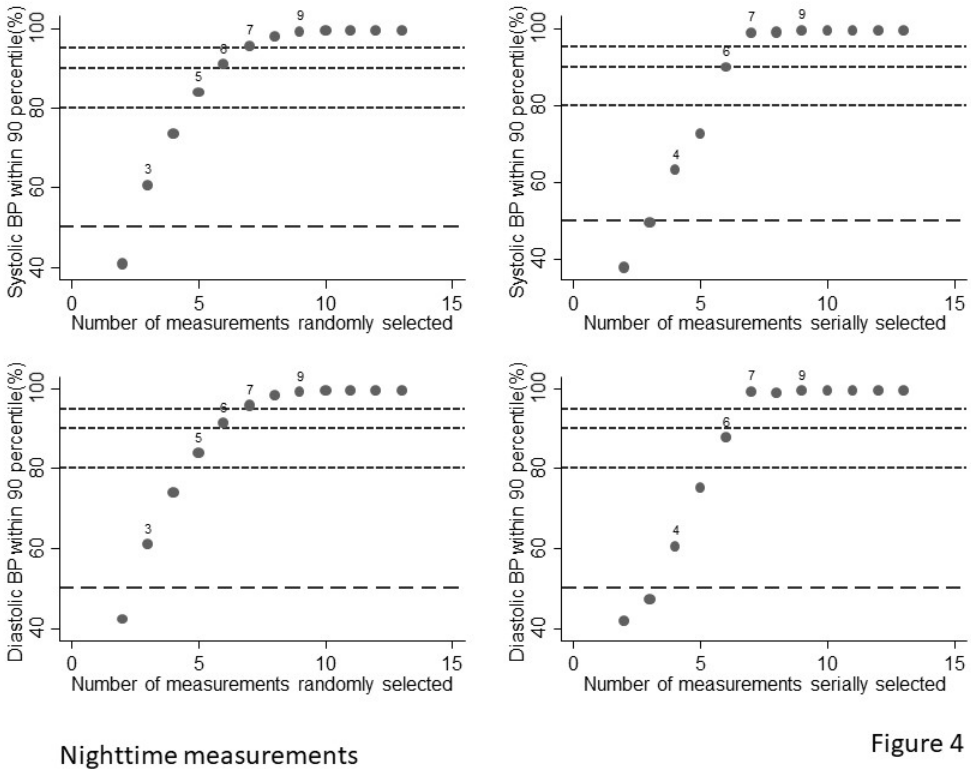


Figure 3 : **Quantitative analysis of agreement of specific BP value with the true level of BP for daytime measurement.** Interpretation of the graph is given in Figure 2 legend except that the data are limited to daytime readings only.



Nighttime measurements

Figure 4

Figure 4: **Quantitative analysis of agreement of specific BP value with the true level of BP for nighttime measurement.** Interpretation of the graph is given in Figure 2 legend except that the data are limited to nighttime readings only.

Table 2: Minimum BP recordings needed for being within 90 percentiles with a certain probability

BP Measure/Probability	50	80	90	95	99
24h systolic random	7	18	30	33	44
24h systolic serial	26	42	47	50	55
Daytime systolic random	5	11	15	18	24
Daytime systolic serial	12	21	24	27	30
Nighttime systolic random	3	5	6	7	9
Nighttime systolic serial	4	6	6	7	9

Chapter Four

Discussion

ABPM is emerging from being predominantly a research tool to one that is mainstream. Although still not used widely the adoption of ABPM is increasing in response to recent recommendations. In the UK, the National Institute of Health and Clinical Excellence (NICE) guidelines endorse its use prior to starting therapy for hypertension (3). The United States Preventive Task Force (USPTF) also recommends its use for making a diagnosis of hypertension (9). Since, ABPM is the reference standard, it is somewhat surprising that no empirical study has asked the question regarding how many readings would represent a valid assessment of 24h ABPM. Our study addresses this gap in our knowledge.

The major findings of the study are as follows: For randomly collected recordings, just 18 readings were needed to be 80% certain that the mean value of systolic BP was within the 90-percentile CI of the true mean. For 90% certainty, this number increased to 26, for 95% certainty, this increased to 33 readings. With 7 recordings, there was a 50% chance that the mean reading will be within the 90 percentile CI of the true mean. Similar results emerged for diastolic BP. With serial selections, in general a greater number of readings were needed to be confident that the mean systolic BP would lie between the 90 percentile CIs of the true mean. The number of readings needed to be 80%, 90% and 95% certain for serial collections were 18, 42, and 47 respectively.

For the diagnosis of hypertension or its absence, surprisingly few recordings were needed. Even with one available recording, whether it be random or serial, the AUC under ROC curve was 0.80 or better. In the case of random selections, there was <2.5% chance that the AUC under ROC was <0.8 for just 1 randomly measured value. With 3 random measures, there was <2.5% chance that the AUC under ROC was <0.9, with 7 random measures there was <2.5% that the AUC under ROC was <0.95, and with 13 random measures there was <2.5% that the AUC under ROC was <0.975. In the case of serial selections, even the first measurement had AUC of 0.85 or better but with wide CIs. For systolic recordings 18 and for diastolic recordings 6 were needed for the lower limit of CI to be >0.9. In contrast to random selection of BP, a greater number of serial recordings were needed to make a diagnosis of hypertension with ambulatory BP monitoring.

There are clinical implications of our finding. The 2013 European Society of Hypertension Guidelines recommend 20 daytime and 7 nighttime recordings to be the minimal number needed to call 24h ABPM adequate (2). Our data suggests that 26 randomly selected recordings is sufficient to provide 90% certainty that the mean systolic or diastolic ABPM will be within 90% CI of the true mean. We believe that if 18 recordings are available over a 24h period—3 more than needed by the CARDIA (5) and IDACO (6) studies—that may be sufficient for a clinical ascertainment of true systolic or diastolic ABPM. To be sure, this does mean that ABPM is abbreviated to just 6 h with three measurements per hour to provide 18 recordings. These would qualify as serial measurements and the number of measurements needed to provide the same certainty

as 18 random recordings would be 42, or approximately 14 h of recordings performed three times an hour. The NICE guidelines recommend at least 14 recordings during the day to make a diagnosis of hypertension (3). Our data confirm that 14 recordings will provide a high degree of reliability in making a diagnosis of hypertension. Specifically, for systolic recordings 14 will provide the lower bound of CI of the area under ROC to be 0.88 and for diastolic recordings 0.925.

Some limitations are acknowledged. The participants were predominantly men. Although there is no *a priori* reason to believe that women would have ABPM test performance that would be significantly different from men, our study should be replicated in a larger group of women. Likewise, all participants with hypertension had CKD. CKD may be associated with increased BP variability and if so, the minimum number of readings needed may be higher than in the general population. However, we had a group of 38 participants with no CKD or hypertension and the results in this group of patients was not substantially different from the overall cohort. Some strengths of the study include its prospective design, selection of ABPM based on adequate number of recordings and a reasonably large number of participants for a single site study.

Chapter Five

Conclusions

In conclusion, in this first empirical study to our knowledge to determine the minimum number of BP recordings needed to validate ABPM. We provide evidence to validate the 2013 European Society of Hypertension guidelines (2) for what is considered an adequate ABPM and NICE guidelines (3) to confirm a diagnosis of hypertension. However, criteria derived from our empirical data are less stringent than the existing guidelines. For making a qualitative decision on making a diagnosis of hypertension or assessing its control a minimum of 18 serial measurements is sufficient. This would require only 6 hour of measurement, thrice per hour instead of twice per hour from 8 AM to 10 PM proposed by NICE guidelines (3). If a 24-hour recording is available and data are missing are random, only 3 measurements are needed to make a qualitative judgment regarding hypertension diagnosis or control. For quantitative analysis, the minimal sufficient number of 24h ambulatory BP is 26 random recordings or 42 serial recordings. Thus, a 14 hour recording with 3 measurements per hour is reasonable to make quantitative decisions which is much less stringent than one proposed by ESH (2).

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Curriculum Vitae
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Academic Appointments

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